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### **EXAMINER'S AMENDMENT**

1. The remarks and declaration under 37 CFR 1.132 filed 17 November 2010 have been entered. Claims 5-11 are pending and under examination.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 November 2010 has been entered.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Pereira on 17 December 2010.

The application has been amended as follows:

In the specification:

At p. 1, the title has been deleted and replaced with - - Methods of Treating Alzheimer's Disease With an Apheresis Device - - -

In the claims:

In claim 5, line 2 delete "in need of such treatment" and replace with - - suffering from or at risk for AD - - -

4. The following is an examiner's statement of reasons for allowance:

The arguments and declaration under 37 CFR 1.132 filed 17 November 2010 are sufficient to overcome the rejection of record under 35 USC 103(a). While the reference by DeMattos suggests that an antibody that binds to A $\beta$  need not enter the CNS to have a therapeutic effect, Dodart et al. 2002 (Nature Neuroscience 5:452-457, submitted with the

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declaration on 17 November 2010) indicate that there would not have been a reasonable expectation of success in performing the method as claimed at the time the invention was made. Specifically, at Figure 4 on p. 454 and in the accompanying descriptive text on p. 455 first paragraph, Dodart et al. provide evidence that when an anti-A $\beta$  antibody is administered in a regime that allows for the A $\beta$  levels in the blood to rise but does not allow the antibody to enter the brain (i.e. 10 or 50  $\mu$ g as in Figure 4), there is no therapeutic effect as the performance of those animals in a learning-related task is no different from controls. The only time a therapeutic effect is seen is when the antibody is administered in a regime such that the antibody enters the CNS. Therefore the reference by Dodart indicates that one of ordinary skill in the art would not have had a reasonable expectation of success in accomplishing the method as claimed.

In the telephone interview of 17 December 2010, the examiner indicated that his copy of the declaration filed under 37 CFR 1.132 was not signed. Mr. Pereira stated that the declaration had been signed, but the signature was not dark, and indicated he would fax a darker copy of the signature page of the declaration to ensure the signature was legible. Examiner Kolker indicated that the new signature page would be scanned in to the file when received.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Frangione et al. (U.S. Patent Application 2009/0175853, published 9 July 2009, filed 5 February 2009, claiming benefit of an application filed on 18 December 2003). The publication teaches but does not claim apheresis as in the presently-claimed method; see for example paragraph [0013]. The underlying application is a continuing application of 2007/0010435, cited in the office action mailed 18 August 2008.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel E. Kolker whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E Kolker/

Primary Examiner, Art Unit 1649

December 20, 2010